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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): SONN:085US

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on February 20, 2009

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Typed or printed name Travis M. Wohlers

Application Number	Filed
10/561,506	December 19, 2005

First Named Inventor: Andreas Meinke

Art Unit	Examiner
1645	OGUNBIYI, Oluwatosin A.

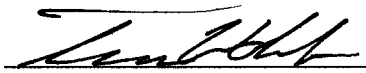
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 57,423.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____



Signature

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Typed or printed name

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Telephone number

February 20, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
ANDREAS MEINKE et al.

Serial No.: 10/561,506

Filed: DECEMBER 19, 2005

For: CHLAMYDIA PNEUMONIAE ANTIGENS

Confirmation No.: 6550

Group Art Unit: 1645

Examiner: OGUNBIYI, Oluwatosin A.

Atty. Dkt. No.: SONN:085US

ARGUMENTS IN SUPPORT OF THE REQUEST FOR PRE-APPEAL BRIEF REVIEW

The Action rejects claims 43, 45, 47-50, and 57 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Action acknowledges that the specification is enabling for an immunogenic composition comprising an amino acid sequence consisting of SEQ ID NO: 91 or a fragment of at least 8 contiguous amino acids of SEQ ID NO: 91, but contends that the specification does not reasonably provide enablement for a pharmaceutical composition or a vaccine composition. In particular, the Action argues that a pharmaceutical/vaccine composition is not enabled because the specification has not demonstrated that the claimed composition can generate a protective immune response *in vivo*. Applicants traverse this rejection.

Contrary to the Action's assertion, the specification does correlate the immunogenicity of SEQ ID NO: 91 and fragments thereof with a protective immune response. SEQ ID NO: 91 was identified from a screen with sera from multiple individuals ***previously infected*** by *C. pneumoniae* (*see e.g.*., p. 13, para. 5 to p. 14, para. 3; Example 4 and Table 2). In other words, this is not an approach in which one started with a candidate antigen, administered it to a subject, and then observed that antibodies were produced. Perhaps with such an approach one might

question whether such an immune response would be relevant to protecting the subject from the pathogen from which the antigen was derived. The approach by which SEQ ID NO: 91 was identified demonstrates the relevance of this antigen in a ***pathogen-induced*** immune reaction in a wide range of patients. Accordingly, the specification correlates the immunogenicity of SEQ ID NO: 91 with protective immune responses against *C. pneumoniae* in multiple humans.

In addition, T cell epitopes were identified in the hyperimmune serum-reactive antigens (*see* Example 5 and Table 1). Thus, the antigen having the amino acid sequence of SEQ ID NO: 91 is not only recognized by antibodies, but also contains predicted T cell epitopes (*see* Table 1). As discussed in the specification, antigens with T cell epitopes are particularly relevant to a *C. pneumoniae* vaccine because *C. pneumoniae* is an intracellular parasite for which a T-cell mediated immune response is important for protective immunity (Specification, p. 15, first full paragraph).

The Thorpe *et al.*, Puolakkainen *et al.,* and Igietseme, *et al.* references cited in the Action show that protective immune responses against Chlamydia have been achieved with antigens identified through genomics and proteomics. In addition, these references demonstrate that *in vitro* and animal models of Chlamydia infection are known to those in the art. Thus, these references provide an indication of the state of the art and the level of skill in the art. In view of the guidance in the specification regarding the evaluation of immune responses to the hyperimmune serum reactive antigens (*see e.g.,* Example 4 and p. 50) and the knowledge of those in the art, someone could make and use a vaccine formulation comprising an isolated hyperimmune serum-reactive antigen comprising an amino acid sequence consisting of SEQ ID NO:91 or a fragment of at least 8 contiguous amino acids of SEQ ID NO: 91 without undue experimentation.

The Action points out that Igietseme *et al.* teaches that some Chlamydia subunit vaccines candidates that have demonstrated immunogenicity *in vitro* provided poor immunogenicity *in vivo* and only partial protective immunity. It is important to note, however, that the present specification demonstrated immunogenicity *in vivo*. Moreover, Igietseme *et al.* teach that a product that provides a partial protective immunity is still considered a "vaccine" and even though it provides partial protective immunity it "would be an acceptable first generation product." (Igietseme *et al.*, page 140).

Applicants further note that "[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) The stage at which an invention in the pharmaceutical field becomes useful is well before it is ready to be administered to humans. *Id.*; *see also Ex parte Zavada*, Board of Patent Appeals and Interferences, Appeal No. 2001-1970 at page 10 ("First, we agree with Appellants that a therapeutic method need not be ready for clinical application in order to be enabled.") (non binding precedent). Accordingly, to the extent the Action may be requiring evidence of clinical efficacy in humans, this is not a requirement for patentability.

In view of the above, the present specification contains a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. Applicants, therefore, respectfully request the withdrawal of the rejection.